

## REMARKS/ARGUMENTS

### Status of the Claims

Claims 12-18, 23-29, and 31-96 are pending. Of these, Claims 39-62, 66-67, and 69-77 are withdrawn from consideration. Claim 64 is amended. Support for the amendment is found throughout the specification, for example at least in paragraphs [0088] and [0089]. Claim 85 is amended. Support for the amendment is found throughout the specification, for example at least in paragraph [0869]. No New Matter is introduced by way of the amendments.

### Rejection under 35 USC §102

Claims 64 and 65 are rejected under 35 USC §102(b) as allegedly being anticipated by Wright (EP 0605963 A2).

A finding of anticipation requires that a single prior art reference must disclose all of the elements of a claim in order to anticipate the invention recited by that claim. *See Manual of Patent Examining Procedure* § 2131. To maintain a *prima facie* case of anticipation, the Examiner must demonstrate that each and every element as set forth in the claim is either expressly found or is inherently described in a single prior art reference. *See MPEP* § 2131. Applicants submit that each element of the claims now pending has not been identified in the art presently of record. Therefore, Applicants respectfully traverse the following rejections.

Claim 64 is directed to:

A glycoPEGylated EPO peptide, said EPO peptide comprising the sequence of SEQ ID NO:73 and further comprising an intact glycosyl linking group linking said EPO peptide and a PEG moiety of said glycoPEGylated EPO peptide.

However, we fail to find such a disclosure in Wright. That is, we have not identified any disclosure in Wright of a glycoPEGylated EPO peptide comprising an intact glycosyl linking group. While Wright discloses that EPO can be coupled via chemical conjugation with PEG, there is no teaching that the resulting EPO conjugate also includes an intact glycosyl linking group linking the EPO peptide and a PEG moiety of the glycoPEGylated EPO peptide. As such, Wright fails to anticipate claim 64. We respectfully request the Examiner to withdraw the rejection.

Claim 65 is directed to:

A glycoPEGylated EPO peptide, said EPO peptide comprising the sequence of SEQ ID NO:73 and further comprising a mutation in said sequence.

However, the Examiner has not pointed to anything in Wright that teaches an EPO comprising a mutation in the sequence. On page 4 of the Office Action the Examiner suggests that the language on page 4 of the application indicates “that one or more of the water soluble reagents may be coupled to individual polypeptides or similar organic molecules, to which would read on a mutant polypeptide of EPO, since only EPO is envisioned in the invention of EP 0605963 A2.” We respectfully disagree.

While the Examiner correctly notes that EPO is mentioned in EP 0605963 A2, there is no disclosure of an EPO comprising a mutation. The language cited by the Examiner also fails to recite an EPO comprising a mutation. In fact, it appears that the Examiner acknowledges this much because the Examiner states that “only EPO is envisioned in the invention of EP 0605963 A2.” Thus, we fail to find any disclosure in the Wright reference that teaches each element of claim 65. As such, we submit that claim 65 is not anticipated; we respectfully request the Examiner to withdraw the rejection.

### **Obviousness-Type Double-Patenting Rejections**

Claims 12-18, 23-38, 63-65, 68 and 78-96 are provisionally rejected on the grounds of nonstatutory obviousness-type double patenting (“ODP”) over claims 1-20, 26, 27, 31-34 of Defrees et al., U.S. Patent 7,405,198. Claims 12-18, 23-38, 63-65, 68 and 78-96 are provisionally rejected on the grounds of nonstatutory obviousness-type double patenting (“ODP”) over claims 1-29 of Defrees et al., U.S. Patent 7,138,371. Claims 12-18, 23-38, 63-65, 68 and 78-96 are provisionally rejected on the grounds of nonstatutory obviousness-type double patenting (“ODP”) over claims 1, 4-18, 26-38, 46, 50, 52-81 of U.S. patent application no. 11/144,223, filed June 2, 2005. Without necessarily commenting on the propriety of the rejections, Applicants are submitting herewith a Terminal Disclaimer. As such, Applicants respectfully request the Examiner to withdraw the rejection.

Claims 12-18, 23-38, 63-65, 68, and 78-96 are provisionally rejected on the grounds of nonstatutory obviousness-type double patenting (“ODP”) over claims 40-44 and 48-52 of U.S. patent application no. 11/440,839, filed May 26, 2006. Applicants respectfully submit that the double patenting issue is not yet ripe with respect to the ‘839 application, which is currently rejected under 35 USC §112, §102, and §103. See September 16th, 2008 Office Action for application ‘839. Having noted the filing

dates of the instant application and the '839 application it can be readily demonstrated that the present application, filed December 5, 2005, is the earlier filed of the two applications. The '839 application was filed May 25, 2006. Pursuant to MPEP 804 I.B., "(i)f a 'provisional' nonstatutory obviousness-type double patenting (ODP) rejection is the only rejection remaining in the earlier filed of the two pending applications, while the later-filed application is rejectable on other grounds, the examiner should withdraw that rejection and permit the earlier-filed application to issue as a patent without a terminal disclaimer." While claims 64 and 65 were rejected under 35 U.S.C. 102, we submit that the rejection has been overcome. As such, the foregoing guideline is applicable because the only remaining rejection would be the ODP rejection; withdrawal of the provisional rejection is respectfully requested.

If the Examiner believes a telephone conference would expedite prosecution of this application, please telephone the undersigned at 415-442-1793. The Commissioner is authorized to deduct any fees associated with this paper from Deposit Account No. 50-0310

Respectfully submitted,



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